

CORRECTED

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 19-1148V

UNPUBLISHED

JANICE ARAGON

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: March 9, 2023

Special Processing Unit (SPU);
Bilateral Shoulder Injury; Influenza
(Flu); Tetanus Diphtheria acellular
Pertussis (Tdap) Vaccine; Shoulder
Injury Related to Vaccine
Administration (SIRVA); Prior
Shoulder Pain; Severity Requirement

Michael Adly Baseluos, Baseluos Law Firm, PLLC, San Antonio, TX, for Petitioner.

Martin Conway Galvin, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT AND CONCLUSIONS OF LAW¹

On August 8, 2019, Janice Aragon filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the “Vaccine Act”). Petitioner alleges that she suffered a shoulder injury related to vaccine administration (“SIRVA”) to both of her shoulders as a result of a Tetanus Diphtheria acellular Pertussis (“Tdap”) vaccine administered to her left deltoid, and an influenza (“flu”) vaccine administered to her right deltoid on October 24, 2017. See Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters (the “SPU”) after Pre-Assignment Review.

¹ Because this unpublished opinion contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the opinion will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

As discussed below, dismissal of the alleged left-side SIRVA claim is warranted, since the record does not substantiate that Petitioner suffered the residual effects of that alleged vaccine-related injury for more than six months after vaccination, as required by Section 11(c)(1)(D)(i) of the Vaccine Act. Petitioner's right-side SIRVA, by contrast, is tenable, but must be pursued outside of SPU.

I. Relevant Procedural History

As noted above, this case was initiated in August 2019. On July 12, 2021, after attempting to resolve this case informally, Respondent filed a status report stating that the parties had reached an impasse, and on July 22, 2021, Petitioner filed a status report seeking guidance on the process for filing a Motion for Ruling on the Record. ECF Nos. 37-38.

At Petitioner's request, I convened a status conference on August 5, 2021, to advise on further proceedings in this case. ECF No. 39. I directed the parties to seek resolution of the matter my motion for ruling on the record, thereby permitting me to address whether Petitioner had established SIRVA Table claims.³ I noted that if I could not find entitlement for Petitioner, I would transfer the case out of SPU (although that would permit Petitioner to seek to prove a non-Table, causation-in-fact claim). *Id.*

On September 20, 2021, Petitioner filed a Motion for Ruling on Record. ECF No. 40. On November 5, 2021, Respondent filed his Rule 4(c) Report and Response to Petitioner's Motion, recommending that entitlement to compensation be denied under the terms of the Vaccine Act. ECF No. 43. As a preliminary matter, Respondent argued that Petitioner failed to establish that she suffered the residual effects of her alleged left shoulder injury for more than six months after vaccination, as required by Section 11(c)(1)(D)(i) of the Vaccine Act. ECF No. 43 at 9-10. Next, Respondent argued that Petitioner had failed to establish that she suffered the Table injury of SIRVA in *either* shoulder, because (a) Petitioner has a history of bilateral shoulder pain, (b) Petitioner has not established that the onset of her shoulder symptoms began within 48 hours of her vaccinations, and (c) Petitioner's pain was not limited to the shoulders in which she received the vaccines. ECF No. 40 at 10-12 (citing 42 C.F.R. § 100.3(c)(10)(i-iii)).⁴ Petitioner filed a Reply brief on November 21, 2021. ECF No. 44.

³ While Petitioner did not explicitly plead a Table injury in her Petition, SIRVA is a recognized injury on the Vaccine Injury Table, accordingly the case was assigned to the Special Processing Unit (wherein I adjudicate Table injuries). Accordingly, once the parties' settlement discussions reached an impasse, Petitioner was ordered to address whether she has established SIRVA Table claims.

⁴ Respondent further argued that Petitioner cannot establish an off-Table claim for her alleged injuries in either shoulder, under the relevant standard. ECF No. 40 at 12-13.

II. Relevant Factual History

A. Medical Records

1. Pre-Vaccination

- On May 12, 2015 (over two years prior to the relevant vaccinations), Petitioner began chiropractic treatment at Comprehensive Injury Treatment Services. Ex. 14 at 4. At that visit, she complained of “remarkably severe constant pulling shoulder pain on both sides” among other symptoms. *Id.* Two days later, on May 14, 2015, Petitioner rated her “constant pulling shoulder pain on both sides” a pain value of 10/10. *Id.* at 5. On examination her right shoulder was positive for a “mild measure of reduced motion” and “[m]oderate tenderness.” *Id.*
- Thereafter, Petitioner was seen for a total of 17 visits at Comprehensive Injury Treatment Services for chiropractic care between May and December 2015. Throughout her treatment Petitioner continued to report subjective complaints of shoulder pain on both sides ranging from 4-10/10. See, e.g., Ex. 14. Petitioner’s objective shoulder findings during this time period included: palpitation revealing “the right shoulder was subluxated with fixation at the joint” (Ex. 14 at 6) and reduced motion and tenderness of the right shoulder (*E.g.*, Ex. 14 at 1-13).
- On July 10, 2015, Petitioner was seen by her primary care provider, Herman Poteet, MD, for right shoulder and scapular pain in addition to other complaints. Ex. 5 at 19. Dr. Poteet indicates in his record that Petitioner suffered “osteoarthritis [that] primarily involve[d] the knees and shoulders and has been slowly progressive.” *Id.* Dr. Poteet noted that Petitioner’s past medical history included “shoulder pain.” *Id.* at 20. In a “Review of Systems,” Dr. Poteet indicated that Petitioner “[a]dmits: shoulder pain.” *Id.* Dr. Poteet’s assessment included “muscle spasm” for which Tinazdine was prescribed *Id.* at 22. Petitioner’s “right scapular pain” was recorded as 5-8/10 and noted to be “worse with barbering, some relief with chiropractic.” *Id.* at 21.
- On November 12, 2015, Dr. Poteet examined Petitioner again, and noted she suffered a history of “muscle spasm right shoulder” and “osteoarthritis” described as “primarily in the knees and shoulders” and as “slowly progressive.” *Id.* at 1. Petitioner’s “shoulder pain” was recorded as “2-3/10” and “worse with activity.” *Id.* at 2. It was noted she “takes tizanidine occasionally.” *Id.* Dr. Poteet’s assessment of Petitioner included “shoulder pain.” *Id.* at 3.

2. Post-Vaccination

- On October 24, 2017, at a visit to establish care with a new primary care provider (Darla Gaye Lowe, M.D.), Petitioner received a flu vaccine in her right deltoid, and a Tdap vaccine in her left deltoid. Ex. 2 at 1, 19-20. At this same visit, Petitioner was also referred for a mammogram and colonoscopy. Ex. 2 at 5-7, 18.
- On October 31, 2017, Petitioner underwent a bilateral mammogram and an ultrasound of the left breast. Ex. 4 at 137-39. A small abnormal mass was identified in Petitioner's left breast that was "suspicious of malignancy." *Id.* at 131, 139.
- On November 9, 2017, Petitioner returned to see Dr. Lowe complaining of "bilateral shoulder discomfort." Ex. 1 at 2. Petitioner indicated the "pain originated 2 weeks ago after receiving [a] flu vaccine and [a] Tdap vaccine." *Id.* Dr. Lowe diagnosed Petitioner with adhesive capsulitis of both shoulders and at Petitioner's request administered bilateral steroid injections which provided "some immediate relief." *Id.* at 1, 5.
- Between November 14, 2017 and January 23, 2018, Petitioner received ongoing treatment related to her left breast mass. See, e.g., Ex. 4 at 171-236. No shoulder complaints were documented during this treatment. However, these records do establish that Petitioner deferred a recommend excision for her left breast mass "due to insurance issues," and that "she did not obtain insurance as she was unable to try out for the academy due to frozen shoulder." *Id.* at 197, 230.
- On May 3, 2018, Petitioner was seen in an Emergency Department, by Justin Wayne Holmes, MD, for "left flank pain." Ex. 4 at 242. No complaints of shoulder pain were recorded at this visit, and a musculoskeletal examination found "[n]ormal range of motion." *Id.* at 244. Petitioner was diagnosed with pyelonephritis (kidney infection). *Id.* at 244-45.
- On May 31, 2018, now more than seven months after the relevant vaccinations, Petitioner was seen by Crystal Dowell, NP, to establish care. Ex. 6 at 1. The record states that Petitioner "developed right shoulder pain weeks ago when she got a shot in that arm. She can't lift very high and had to quit her job as a hair dresser because of it." *Id.* Petitioner was assessed with "right shoulder pain," prescribed Mobic, and referred to an orthopedist. *Id.* at 2. This record contains no mention of any left shoulder pain or left shoulder injury.
- On June 25, 2018, eight months after her vaccinations, Petitioner was seen by orthopedist, Jacob Battle, MD, for a chief complaint of "right shoulder pain." Ex. 6 at 9. It was noted that her "[s]ymptoms began after receiving a flu shot in November." *Id.* A right shoulder exam found that her shoulder was "severely limited by pain." *Id.* at 10. Dr. Battle diagnosed Petitioner with "[r]ight shoulder adhesive capsulitis." *Id.* Dr. Battle indicated that while he did not "understand the direct correlation between the flu shot and her onset of adhesive capsulitis," he indicated

Petitioner “is a diabetic and this predisposes her to the shoulder issue of adhesive capsulitis.” *Id.* Dr. Battle recommended physical therapy and a home exercise program. *Id.*

- No further medical record discuss Petitioner’s alleged vaccine related bilateral shoulder pain, although she was seen by medical providers for unrelated issues.

B. Petitioner’s Declarations

Petitioner filed two declarations on August 8, 2019 and December 16, 2019, styled as affidavits, describing her pre-vaccination shoulder pain, her October 24, 2017 vaccinations, subsequent treatment, and pain and suffering. Exs. 7, 12.⁵ Petitioner states she suffered pain in her shoulders immediately following the relevant vaccinations. Ex. 7, ¶ 8; Ex. 12 at 1. Petitioner indicates she was not able to seek treatment between November 9, 2017 and May 30, 2018, due to financial reasons. Ex. 12 at 1. She adds that her left shoulder “fully recuperated around June 2018,” but that she “continues to feel pain in [her] right shoulder,” although she has been unable to return to treatment for her “shoulder injuries since June 25, 2018 due to a lack of insurance coverage and inability to pay for care out-of-pocket.” *Id.* at 1-2. Petitioner states that she was unable to continue her job as a hair stylist as her shoulder injuries prevent her from “lifting [her] arms during extended periods.” *Id.* at 2; see Ex. 7, ¶ 12.

In regard to her past shoulder pain, Petitioner indicates that in “July of 2015, I sought medical attention for pain between my shoulder blades. The pain between my shoulders was caused by repetitive motions required by my prior employment as a hair stylist.” Ex. 12 at 1. Petitioner elaborates that her “interscapular pain was unrelated to the arm-shoulder pain that I later developed as a result of the vaccinations.” *Id.*

III. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner’s injury or illness that is contained in a medical record. Section 13(b)(1). “Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally

⁵ I observe that neither of Petitioner’s statements were notarized. Petitioner’s declaration filed on August 8, 2019 was signed “under penalty of perjury” (Ex. 7), however Petitioner’s declaration filed on December 16, 2019 was merely signed, but not done so “under penalty of perjury” (Ex. 12).

contemporaneous to the medical events.” *Cucuras v. Sec’y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec’y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. “Written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent.” *Murphy v. Sec’y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 74931, *4 (Fed. Cl. Spec. Mstr. April 25, 1991), quoted with approval in decision denying review, 23 Cl. Ct. 726, 733 (1991), *aff’d per curiam*, 968 F.2d 1226 (Fed.Cir.1992)). And the Federal Circuit recently “reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient’s physical conditions.” *Kirby v. Sec’y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021).

The United States Court of Federal Claims has outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person’s failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional’s failure to document everything reported to her or him; (3) a person’s faulty recollection of the events when presenting testimony; or (4) a person’s purposeful recounting of symptoms that did not exist. *La Londe v. Sec’y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff’d*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is “consistent, clear, cogent, and compelling.” *Camery v. Sec’y of Health & Hum. Servs.*, 42 Fed. Cl. 381, 391 (1998) (citing *Blutstein v. Sec’y of Health & Hum. Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such fact testimony must also be determined. *Andreu v. Sec’y of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec’y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred “within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period.” Section 13(b)(2). “Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table.” *Id.*

The special master is obligated to fully consider and compare the medical records, testimony, and all other “relevant and reliable evidence contained in the record.” *La Londe*, 110 Fed. Cl. at 204 (citing Section 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec’y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master’s discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

IV. Findings of Fact and Dismissal of Left Shoulder Claim

A threshold issue is presented in regard to Petitioner’s left-side SIRVA claim—whether Petitioner suffered the residual effects of her alleged vaccine-related injury in her left shoulder for more than six months after vaccination, as required by Section 11(c)(1)(D)(i) of the Vaccine Act.

In this case, it is undisputed that Petitioner received a Tdap vaccination on October 24, 2017, in her left deltoid. Thereafter, she complained of bilateral shoulder pain on November 9, 2017, indicating it began two weeks ago, in the period after the vaccinations. Ex. 1 at 2. Her subsequent medical records, however, contain no further complaints of left shoulder pain, although she did continue to complain of pain in her right shoulder.

Thus, on May 31, 2018, Petitioner was examined by NP Dowell, and the record of that visit details that Petitioner “developed *right shoulder pain* weeks ago when she got a shot in that arm,” but does not mention left-side pain. Ex. 6 at 1 (emphasis added). A physical examination of Petitioner’s extremities indicates: “No edema. Is only able to raise right arm about 60 degrees. C[omplains] o[f] pain in deltoid. None in shoulder joint.” *Id.* at 2. Petitioner presented again with a chief complaint of “right shoulder pain” only to orthopedist, Dr. Battle, on June 25, 2018. Ex. 6 at 9. Dr. Battle indicated that her “symptoms began after receiving a flu shot in November.” *Id.* A right shoulder exam found that her shoulder was “severely limited by pain.” *Id.* at 10. Dr. Battle diagnosed Petitioner with “[r]ight shoulder adhesive capsulitis.” *Id.*

I have frequently found that the failure of a medical record to document a complaint, symptom, or injury does not preclude a finding that the injury/symptom occurred. Thus, I have found onset, and severity, satisfied in other SIRVA cases despite a delay in seeking treatment initially, failure to report pain or symptoms at certain medical visit, or gaps in a petitioner’s treatment course. I credit Petitioner’s explanation herein that she was uninsured during this time frame. I also acknowledge that it is common for medical records documenting specialized care or treatment, such as the medical records corresponding to Petitioner’s treatment of a left breast mass between November 14, 2017

and January 23, 2018, to not address matters that are not related to the specialized or urgent issue.

Nevertheless - the evidence that Petitioner's left shoulder pain and/or injury persisted beyond November 2017 is extremely minimal. The medical records document that Petitioner reported experiencing left shoulder pain only once – thirteen days after her vaccinations – on November 13, 2017. If both were occurring still by the spring of 2018, it is more likely than not that Petitioner would have so reported to a treater – but she only reported *right*-side shoulder pain. Thus, Petitioner's allegation that her left shoulder pain persisted for more than six months is not supported by the medical record, or *any* other evidence, absent her own uncorroborated statement.

Accordingly, because she cannot meet the Act's severity requirement for her left-side SIRVA, and because severity applies equally to Table and non-Table claims, **Petitioner's left shoulder injury claim is dismissed.**

V. Reassignment of Petitioner's Right Shoulder Claim

In regard to Petitioner's right shoulder claim, Respondent has asserted that Petitioner has not demonstrated the necessary QAI requirements to establish a SIRVA Table case.⁶ Specifically Respondent asserts that (a) Petitioner has a history of bilateral

⁶ The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, provides the criteria for establishing a Table SIRVA as follows:

Shoulder injury related to vaccine administration (SIRVA). SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:

- (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
- (ii) Pain occurs within the specified time-frame;
- (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and

shoulder pain, (b) Petitioner has not established that the onset of her shoulder symptoms began within 48 hours of her vaccinations, and (c) Petitioner's pain was not limited to the shoulders in which she received the vaccines. ECF No. 40 at 10-12 (discussing the first three QAI requirements for a Table SIRVA case pursuant to 42 C.F.R. § 100.3(c)(10)).

My preliminary review of the records (and specifically Petitioner's pre-vaccination records discussed above) indicate some evidence that Petitioner's shoulder pain predated her vaccination. However, Petitioner should be afforded an opportunity to establish that such pre-existing pain was not related to her post-vaccination right shoulder pain, and that she can meet the Table elements. Alternatively, Petitioner may be able to establish a significant aggravation claim. Regardless, the factual inquiry required to bulwark the right-side claim cannot be appropriately resolved in SPU, and therefore the matter must be transferred.

Conclusion

Petitioner has not provided preponderant evidence to establish that she suffered the sequela of her left shoulder injury for more than six months. Accordingly, Petitioner's left shoulder injury claim is dismissed. Pursuant to Vaccine Rule 3(d), I will issue a separate Order reassigning this case out of SPU for the resolution of Petitioner's right shoulder claim.

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran
Chief Special Master

(iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).